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September 30, 2013

**VIA CM/ECF & HAND DELIVERY**

The Honorable Richard G. Andrews  
U.S. District Court for the District of Delaware  
844 North King Street, Room 6325, Unit 9  
Wilmington, DE 19801-3555

PUBLIC VERSION FILED:  
October 7, 2013

**Re: *Novartis Pharmaceuticals Corp. v. Alvogen Pine Brook, Inc.*  
1:11-cv-00052-RGA (Consolidated)**

Dear Judge Andrews,

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On behalf of Plaintiffs, and further to a discussion between counsel and Your Honor's chambers on September 18, 2013, we write to seek assistance with a discovery dispute in the above-referenced Hatch-Waxman drug patent case.

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The case concerns Alvogen's abbreviated new drug application ("ANDA") under which Alvogen seeks FDA approval to make and sell generic versions of Plaintiffs' Exelon® Patch product. Plaintiffs sued Alvogen for infringement of U.S. Patents Nos. 6,316,023 and 6,335,031—the same two patents that are the subject of District of Delaware Civil Action No. 11-1077-RGA, which was tried before Your Honor from August 26-29, 2013. As the Court will recall from the trial in that case, the claims of the '023 and '031 patents require an antioxidant.

Since May 28, 2013, Plaintiffs have sought from Alvogen and its ANDA product manufacturer, [REDACTED] samples of Alvogen's accused ANDA products and the components used in such products to determine whether the products and components contain an antioxidant. See Exh. 1 (request nos. 55-79), Exh. 2 (subpoena category nos. 3-12, 15, 17, 19, 21, 23, 25, 27, 28, 30, 32, 36, 38, 40-42). Over the past four months, Alvogen and [REDACTED] have repeatedly resisted those requests through their common counsel, Axinn Veltrop.<sup>1</sup> A history of the dispute follows.

1. In their June 2013 responses to Plaintiffs' May 28, 2013 requests, Alvogen and [REDACTED] each asserted that the requests were overbroad, irrelevant, and/or sought material available from "other" sources. Exhs. 3 and 4. Together, Alvogen and

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<sup>1</sup> Plaintiffs have requested, but have not yet received, the agreement between Alvogen and [REDACTED] relating to Alvogen's ANDA products. Regardless, as Alvogen is the entity that will commercially market the accused ANDA products in the United States, it stands to reason that Alvogen must have control of those products and the components thereof.

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█████ agreed only to produce 100 patches of each dosage strength of the accused ANDA products, far less than the amounts requested by Plaintiffs.

2. On July 2, 2013, Plaintiffs requested clarification as to whether Alvogen and/or █████ would produce the requested component samples, and what “other” sources were able to provide such samples. Exh. 5. On July 9, 2013, Axinn Veltrop responded with two letters: one on behalf of Alvogen (Exh. 6) asserting that while Alvogen did not have any of the requested component samples in its possession, custody or control, Plaintiffs could “easily purchase such materials in the quantities requested from the same commercial suppliers”; the other on behalf of █████ (Exh. 7) asserting that █████ would need to negotiate a protective order separate from the one previously entered before it produced any material in this case.

3. On July 12, 2013, following a discovery conference before Your Honor, Josephine Liu, formerly of Axinn Veltrop, told Plaintiffs’ counsel Filko Prugo that a “bankruptcy” might impair the production of the requested materials. On July 19, 2013, Plaintiffs sent a letter seeking clarification as to how the bankruptcy would impair such production. Exh. 8. Plaintiffs received no response to that letter, and had to send a follow-up letter on August 3, 2013. Exh. 9.

4. On August 9, 2013, Axinn Veltrop responded on behalf of █████ by asserting that the requested component samples were not relevant because the claims of the ‘023 and ‘031 patents were directed to “compositions that contain an antioxidant and transdermal devices” not the “components that comprise” such compositions. Exh. 10. In that letter, █████ now asserted that some, but not all, of the components requested were commercially available from vendors disclosed in Alvogen’s ANDA. In a letter dated August 12, 2013, Alvogen repeated its relevancy objection. Exh. 11.

5. In an email dated August 14, 2013, Plaintiffs sought to arrange a meet-and-confer with Axinn Veltrop to confirm that Alvogen and █████ would not produce the requested component samples. Exh. 12. On August 22, 2013, Axinn Veltrop sent Plaintiffs a letter that did not mention the requested component samples and instead asked “what additional issues Plaintiffs contend remain.” Exh. 13.

6. On September 5, 2013, Plaintiffs sent Axinn Veltrop a letter informing it that Alvogen’s and █████ ongoing refusal to produce the requested component samples left Plaintiffs no choice but to subpoena the third-party suppliers and to seek the Court’s assistance. Exh. 14. Plaintiffs subpoenaed several of those third-party component suppliers on September 9, 2013. D.I. 49.

7. On September 19, 2013, Axinn Veltrop, on behalf of █████, informed Plaintiffs for the first time that █████ would agree to produce five of the requested components in certain quantities, four of which were far less than the requested amounts. Exh. 15. The parties conducted a meet-and-confer on September 26, 2013 and could not resolve their differences. Of note, Axinn Veltrop asserted that the originally requested sample quantities were excessive and alleged that the production of the originally requested quantities would create an undue burden on █████.

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Despite that assertion, however, Axinn Veltrop admitted it had not investigated and could not identify specifically what the undue burden is.<sup>2</sup>

Moreover, it is clear that both Alvogen's and [REDACTED] relevancy objections are without merit. The '023 and '031 patents require an antioxidant. Plaintiffs clearly are entitled to the requested samples of Alvogen's ANDA products and the components that are used to make that product in order to determine whether they contain an antioxidant.<sup>3</sup> And, despite the service of subpoenas on the third-party suppliers of those components, Plaintiffs have no assurance that all third-party suppliers will comply with the subpoenas and produce the requested component samples, which could lead to motions to compel in several different district courts and substantially delay the progression of this litigation. Notably, Plaintiffs have attempted to purchase samples of key components of Alvogen's ANDA products directly from the suppliers, and have been unsuccessful.

The amounts of Alvogen's ANDA products and the components thereof that Plaintiffs have requested are reasonable and are similar to those produced by the Defendants in Delaware Civil Action No. 11-1077-RGA. For example, Plaintiffs requested from Alvogen [REDACTED] the production of 1 kg of [REDACTED] used in Alvogen's ANDA products. 1 kg is the same amount of [REDACTED] that Plaintiffs requested, and that Watson produced, in Delaware Civil Action No. 11-1077-RGA. To date, [REDACTED] has offered to produce only 20 grams of [REDACTED] used in Alvogen's ANDA products—just 2% of the requested 1 kg amounts. The 20 gram amounts offered by [REDACTED] are insufficient to run the tests presently contemplated by Plaintiffs' expert.

Alvogen's and [REDACTED] objections to Plaintiffs' requests are further diminished by the fact that Plaintiffs have agreed to pay for the materials. Exh. 8. Plaintiffs' willingness to pay for these materials also underscores Plaintiffs' genuine belief that the materials and quantities requested are both relevant and reasonable.

Given the clear relevance and reasonableness of the requested discovery to this case, and the failure of Alvogen or [REDACTED] to advance any credible reason for their ongoing resistance to the requested discovery, Plaintiffs respectfully request that Alvogen and/or [REDACTED], within 14 days of this Court's Order, produce the requested samples of Alvogen's accused ANDA products and the components thereof, as set forth in the enclosed proposed Order.

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<sup>2</sup> The fact [REDACTED] is a third party is of no import here. See March 6, 2013 Rule 16 Conference Tr. (D.I. 25) at 13:5-14 ("THE COURT: All right. So I think I understand you're saying that essentially a subpoena [REDACTED] will be treated roughly the equivalent of a discovery request to a party. I would imagine that's no problem for the plaintiff. Is that what you're saying, Mr. Landmon? MR. LANDMON: That is what I'm saying, Your Honor. I just want to make it clear we would need some formal document served on us. That was it.").

<sup>3</sup> Plaintiffs note that Alvogen's counsel attended the August 26-29, 2013 trial in Delaware Civil Action No. 11- 1077-RGA, which indisputably established the relevance of the components of the accused ANDA product to the infringement of the '023 and '031 patents, as both Plaintiffs' and Defendants' experts agreed that such testing informed the infringement analysis.

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Respectfully Submitted,

*/s/ Daniel M. Silver*

Daniel M. Silver (#4758)

cc: Counsel of record (via electronic mail)